

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,

Plaintiff/Counter-Defendant,

v.

BLUEWILLOW BIOLOGICS,
INC.,

Defendant/Counter-Plaintiff.

Case No. 2:21-cv-10312

HONORABLE STEPHEN J. MURPHY, III

**ORDER DENYING
MOTION FOR LEAVE TO AMEND COMPLAINT [28]**

Plaintiff Trutek Corporation moved to amend the complaint. ECF 28. The proposed amended complaint sought to add allegations about Defendant Bluewillow's vaccine products that allegedly infringed on Trutek's patents. ECF 28-3, PgID 329–36. Defendant opposed the motion for leave to amend. ECF 30. For the following reasons, the Court will deny the motion to amend.¹

Federal Rule of Civil Procedure 15(a)(2) provides that after a responsive pleading is filed, a party may only amend a pleading with the written consent of the opposing party or with leave of the Court. The rule also provides that “[t]he [C]ourt should freely give leave when justice so requires.” *Id.*; see *Foman v. Davis*, 371 U.S. 178, 182 (1962). To determine whether to grant leave to amend a pleading, the Court relies on six factors: (1) “undue delay in filing”; (2) “lack of notice to the opposing

¹ Based on the parties' briefing, the Court will resolve the motion on the briefs without a hearing. See Fed R. Civ. P. 78(b); E.D. Mich. L.R. 7.1(f)(2).

party”; (3) “bad faith by the moving party”; (4) “repeated failure to cure deficiencies by previous amendments”; (5) “undue prejudice to the opposing party”; and (6) “futility of [the] amendment.” *Wade v. Knoxville Utils. Bd.*, 259 F.3d 452, 458–59 (6th Cir. 2001) (quotation omitted).

A proposed amendment is futile if the complaint could not survive a motion to dismiss. *Id.* As a result, the proposed amended complaint must allege facts “sufficient ‘to raise a right to relief above the speculative level,’ and to ‘state a claim to relief that is plausible on its face.’” *Hensley Mfg. v. ProPride, Inc.*, 579 F.3d 603, 609 (6th Cir. 2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007)).

The Court views the proposed amended complaint in the light most favorable to the plaintiff, presumes the truth of all well-pleaded factual assertions, and draws every reasonable inference in the nonmoving party’s favor. *Bassett v. NCAA*, 528 F.3d 426, 430 (6th Cir. 2008). But the Court will not presume the truth of legal conclusions. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). If “a cause of action fails as a matter of law, regardless of whether the plaintiff’s factual allegations are true or not,” then the Court must dismiss. *Winnett v. Caterpillar, Inc.*, 553 F.3d 1000, 1005 (6th Cir. 2009).

The Court will deny leave to amend because the new allegations that involve Defendant’s vaccines are protected under the safe harbor provision of 35 U.S.C. § 271(e)(1). The statute provides:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1). The safe harbor “extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the [Food, Drug, and Cosmetic Act].” *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (emphasis in original).

To avoid dismissal under the safe harbor, Plaintiff must plausibly allege that Defendant is engaging, or has engaged, in infringing activities that do not fall within the § 271(e) safe harbor. *See Med. Diagnostic Labs., L.L.C. v. Protagonist Therapeutics, Inc.*, 298 F. Supp. 3d 1241, 1249 (N.D. Cal. 2018) (“Although whether challenged activity is reasonably related to the development and submission of information for FDA approval may in some circumstances be a fact question, there must be specific facts alleged to create a plausible claim to the contrary in order to escape dismissal under the safe harbor provision.”) (citation omitted).

Defendant’s vaccines plainly fall into the safe harbor provision. As the proposed amended complaint stated, “[Defendant] is currently developing vaccines.” ECF 28-3, PgID 331. The several vaccines that allegedly infringed on Plaintiff’s patents are in “ongoing” development and are “currently undergoing phased trials to determine safety and efficacy.” *Id.* at 332. And Defendant “has not yet realized revenue from sales of its vaccine products.” *Id.*

“Activities carried out to satisfy FDA requirements fall within the safe harbor.” *Classen Immunotherapies, Inc. v. Shionogi, Inc.*, 993 F. Supp. 2d 569, 576 (D. Md. 2014). And Defendant has not yet obtained approval for any vaccine that it has allegedly developed with Plaintiff’s patented technology. *See* ECF 28-3, PgID 329–36.

Thus, Defendant's alleged use of Plaintiff's technology falls squarely in the safe harbor provision because "there is a reasonable basis for believing that the experiments will produce the types of information that are relevant to an investigational new drug application or new drug application." *Merck KGaA*, 545 U.S. at 208 (cleaned up); see, e.g., *Enteris Biopharma, Inc. v. Clinical Pharmacology of Miami, Inc.*, No. 1:14-cv-22770, 2015 WL 12085848, at *8 (S.D. Fla. Mar. 20, 2015) (granting a motion to dismiss because the complaint alleged that the defendants committed patent infringement by conducting a clinical trial connected to filing a new drug application with the FDA); *Teva Pharms. USA, Inc. v. Sandoz Inc.*, No. 09-cv-10012, 2013 WL 3732867, at *4–9 (S.D.N.Y. July 16, 2013) (same).

Last, Plaintiff's response to the futility argument suggested only that safe harbor is an affirmative defense. ECF 31, PgID 510. Although safe harbor is an affirmative defense, a defendant may still raise it as proper grounds for Rule 12(b)(6) dismissal. *Enteris Biopharma, Inc.*, 2015 WL 12085848, at *7 (collecting cases). The Court will therefore deny the motion for leave to amend the complaint based on futility.

WHEREFORE, it is hereby **ORDERED** that the motion for leave to amend the complaint [28] is **DENIED**.

SO ORDERED.

s/ Stephen J. Murphy, III
STEPHEN J. MURPHY, III
United States District Judge

Dated: June 2, 2022

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was served upon the parties and/or counsel of record on June 2, 2022, by electronic and/or ordinary mail.

s/ David P. Parker
Case Manager